IAP10 Rec'd PCT/PTO 02 DEC 2005

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Date of Deposit

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1630

CAMPION ET AL.

APPLICATION NO: 10/537,869

FILED: JULY 6, 2005

FOR: COMBINATIONS OF VALSARTAN WITH COX-2 INHIBITORS

MS: PCT

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

#### RESPONSE TO NOTICE TO FILE MISSING PARTS

Sir:

The Notice to File Missing Parts of Application mailed October 6, 2005 (a copy of which is enclosed) has a shortened statutory time set to expire on December 6, 2005.

In response, applicants submit that on July 6, 2005 an original fully executed Declaration and Power of Attorney was submitted with a Transmittal Letter stating that this is a Second or Subsequent Submission of items concerning a filing under 35 U.S.C 371 and the surcharge fee under 37 CFR § 1.16(e) of \$130.00 was authorized to be charged to Deposit Account No. 19-0134 in the name of Novartis Corporation. Copies of the submission dated July 6, 2005 as well as the returned postcard indicating that these papers were sent and received by the Patent and Trademark Office (PTO), PCT Branch are enclosed herewith. It is noted, that on October 31, 2005 a Notice of Acceptance of Application under 35 U.S.C 371, dated October 25, 2005 was received by Applicants confirming that all the requirements have been received in the PTO (a copy is enclosed herewith).

It is believed that no additional fee is necessary. However, the Commissioner is hereby authorized to charge any fees under 37 CFR §1.17 which may be required, or credit any overpayment, to Account No. 19-0134 in the name of Novartis.

Respectfully submitted,

Novartis

Corporate Intellectual Property One Health Plaza, Building 104 East Hanover, NJ 07936-1080 (862) 778-7831

Date:

12/1/05

Gregory D. Ferrand

Attorney for Applicants Reg. No. 36,134

| Case No. PC/4-32P/PA  |
|---|
| Application No. 10/537, 869   |
| Mailing Date: 7/6/05  |
| Due Date: JCO4 Rec'd PCT/PTO 06 JUL 2005  |
| Express Mail No.: EV 524615577 US   |
| The Patent & Trademark Office acknowledges, and has stamped   |
| hereon the date of receipt of the items checked below:  |
| ☐ Amendment/Response/Letter - Fee \$  |
| ☐ Appln. Filing Papers - Fee \$   |
| ☐ PCT National Stage  |
| ☐ Provisional Application   |
| □ RCE □ DIV □ CONT □ CIP  |
| Specification Pg's 130,00   |
| Executed/University Decl Fee \$ 130,00  |
| Missing Parts/Wissing Neq.  |
| Claim of Priority C Certified Copy(8) 12 13 70  |
| Executed/Unexpensed Decl Fee \$   |
| □ Notice of Appeal - Fee \$   |
| ☐ Appeal Brief - Fee \$   |
| ☐ Issue Fee Payment \$ \$   |
| ☐ Issue Fee Payment \$  |
| ☐ Formal Drawings — Pg's Fee \$ Unda C. Rothwell  |
| DIDSPg's - Fee \$Patent   |
| □ PTO-1449 FormPg's CO  |
| ☐ IDS Pg's - Fee \$ Pg's ☐ PTO-1449 Form Pg's ☐ Pet. for Ext. of Time - Fee \$ Application Data Sheet |
| ☐ Seq. Listings Pg's/Seq. Disk  |
|   |
| <u> </u>  |
| <u>GD</u> Y   |
| Initials 82972/99A Rev.1  |

|   |  | Department of Commerce Patent and Trademark Office | ATTORNEY'S DOCKET NUMBER                        |  |  |  |  |  |
|---|--|--|---|--|--|--|--|--|
| (REV 10-96)   |  |  | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) |  |  |  |  |  |
|   | TRANSMITTAL LETTER TO T  | 10/537,869   |   |  |  |  |  |  |
| DESIGNATED/ELECTED OFFICE (DO/EO/US)  CONCERNING A FILING UNDER 35 U.S.C. 371   |  |  |   |  |  |  |  |  |
| INTER   | NATIONAL APPLICATION NO.   | PRIORITY DATE CLAIMED                              |   |  |  |  |  |  |
| PCT/EP03/14406 17 December 2003 (17.12.03) 18 December 2002 (18.12.02)  |  |  |   |  |  |  |  |  |
| TITLE OF INVENTION COMBINATIONS OF VALSARTAN WITH COX-2 INHIBITORS  |  |  |   |  |  |  |  |  |
| APPLICANT(S) FOR DO/EO/US   |  |  |   |  |  |  |  |  |
| CAMPION ET AL.  |  |  |   |  |  |  |  |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |  |  |   |  |  |  |  |  |
| <ol> <li>This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</li> <li>This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</li> <li>This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).</li> <li>A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority</li> </ol> |  |  |   |  |  |  |  |  |
| 5. 🗆  | <ul> <li>a.  is transmitted herewith (required only if not transmitted by the International Bureau).</li> <li>b.  has been transmitted by the International Bureau. (See Form PCT/IB/308)</li> <li>c.  is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ul>   |  |   |  |  |  |  |  |
| 6.<br>7.  | A translation of the International Application into English (35 U.S.C. 371(c)(2)).  Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C.371(c)(3)).  a. are transmitted herewith (required only if not transmitted by the International Bureau).  b. have been transmitted by the International Bureau.  c. have not been made; however, the time limit for making such amendments has NOT expired. |  |   |  |  |  |  |  |
| 8.<br>9.<br>10.   | d. have not been made and will not be made.  A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).  An executed Declaration and Power of Attorney (original or copy) (35 U.S.C. 371(c)(4)).  A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).   |  |   |  |  |  |  |  |
| Items 11. to 16. below concern document(s) or information included.   |  |  |   |  |  |  |  |  |
| 11. 🗆   | An Information Disclosure Statement und  | ler 37 CFR 1.97 and 1.98.                          |   |  |  |  |  |  |
| 12. 🗆   | An assignment document for recording.  | A separate cover sheet in compliance               | with 37 CFR 3.28 and 3.31 is included.          |  |  |  |  |  |
| 13.   | A FIRST preliminary amendment. A SECOND or SUBSEQUENT preliminar   | y amendment.                                       |   |  |  |  |  |  |
| 14.   | An Application Data Sheet under 37 CFR   | <b>1.76.</b>                                       |   |  |  |  |  |  |
| 15. 🔲   | A substitute specification.  |  |   |  |  |  |  |  |
| 16. 🔲   | A change of power of attorney and/or add   |  |   |  |  |  |  |  |
| 17.   | A computer-readable form of the sequence   |  | •   |  |  |  |  |  |
| 18. 🗌   | A second copy of the published Internation   |  |   |  |  |  |  |  |
| 19. 🔲   | A second copy of the English language tr   | anslation of the International application         | on under 35 U.S.C. 154(d)(4).                   |  |  |  |  |  |

20. Other items or information:

| U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/537,869  | INTERNATIONAL APPLICATION NO. PCT/EP03/14406   |                                    | PC/4-3281      | OCKET NUMBER      |                                       |  |
|---|--|------------------------------------|----------------|-------------------|---------------------------------------|--|
| The following fees are submitted:   |  |                                    |                | CALCULATION       | IS emples                             |  |
| 7110 1011011111g 1000 E. O  |  |                                    |                | ONLY              | PIOUSE                                |  |
| 21. Basic national fee  |  |                                    |                |                   | İ                                     |  |
| 22. Examination Fee   |  |                                    |                |                   |                                       |  |
| If International preliminary exam   | ination report was prepared by U   | ISPTO                              | •              |                   |                                       |  |
| and all claims satisfy provisions   |  |                                    | \$             |                   | <b>!</b>                              |  |
|   |  |                                    | •              |                   |                                       |  |
| All other situations  |  | • • • • • • •                      | \$             |                   |                                       |  |
|   |  |                                    | ·····          |                   |                                       |  |
| 23. Search fee  | 2)) has been poid on the internat  | ional                              |                |                   | ĺ                                     |  |
| If Search fee (37 CFR 1.445(a)(2<br>application to the USPTO as an  | International Searching Authority  | 1011a1<br>/                        | s              |                   |                                       |  |
| If International Search Report wa   | as prepared and provided to the  | Office                             | \$<br>\$       | 1                 |                                       |  |
| All other situations  |  |                                    | \$             |                   |                                       |  |
|   |  |                                    |                |                   | ·                                     |  |
|   | AL OF 21, 22 AND 23 =  |                                    |                | \$ 0              |                                       |  |
| Additional fee for specification and drawings<br>program listing filed in an electronic medium  | tiled in paper over 100 sheets (   | excluding sequ                     | ence listing ( | or computer       | ·                                     |  |
| program listing filed in an electronic medium thereof.  | ij. The ree is <b>⊅∠50</b> for each addi   | ilional JU Sneet                   | a oi paper oi  | nacuon            | [                                     |  |
|   | er of each additional 50 or fraction   | n R                                | ATE            |                   |                                       |  |
|   | (round up to a whole number)   |                                    | · .            |                   |                                       |  |
| - 100 =   /50 =   |  | X \$                               | 250            | \$                |                                       |  |
|   | d== ===4 ==  |                                    |                |                   |                                       |  |
| Surcharge of \$130 for furnishing the oath of months from the earliest claimed priority dat   | declaration later than 30  |                                    |                | \$ 130            |                                       |  |
| CLAIMS NUMBER FILE  | D NUMBER EXTRA   | RAT                                | E              |                   |                                       |  |
| 00  | 20 =   | X \$                               | 50             | \$                |                                       |  |
| Independent claims  | 3 =  | X \$                               | 200            | \$                |                                       |  |
| MULTIPLE DEPENDENT CLAIM(S) (if appli   | cable)   | + \$                               | 360            | \$                |                                       |  |
|   | TOTAL OF ABOVE   | CALCULA                            | TIONS =        | \$ 130            |                                       |  |
| Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).   |  |                                    |                |                   |                                       |  |
| filed (Note 37 CFR 1.9, 1.27, 1.28).  |  | SUB                                | TOTAL =        | \$ 130            |                                       |  |
| Processing fee of \$130 for furnishing the En   | olish translation later than   |                                    |                |                   |                                       |  |
| earliest claimed priority date (37 CFR 1.492)   | f)).   |                                    | +              | \$                |                                       |  |
|   |  | AL NATION                          | AL FEE =       | \$ 130            |                                       |  |
| Fee for recording the enclosed assignment (   | 37 CFR 1.21(h)). The assignment  | ent must be ac                     | companied      |                   | · · · · · · · · · · · · · · · · · · · |  |
| by an appropriate cover sheet (37 CFR 3.28  | , 3.31). <b>\$40</b> per property  |                                    | +              | \$                |                                       |  |
|   | TOTAL  | FEES ENC                           | LOSED =        | \$ 130            |                                       |  |
|   |  |                                    | ·              | Amount to         | [\$                                   |  |
| •   |  |                                    |                | be: refunded      |                                       |  |
|   |  | <u> </u>                           | <del></del>    | charged           | \$                                    |  |
| a. A check in the amount of \$  | to cover the above fee   |                                    |                |                   | •                                     |  |
| <ul> <li>b. Please charge Deposit Account No. duplicate copy of this form is enclosed.</li> </ul>   | Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of \$130 to cover the above fees. A  |                                    |                |                   |                                       |  |
| ,   |  | es which mav                       | be required.   | or credit any ove | erpayment to                          |  |
| Deposit Account No. 19-0134 in the  | The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0134 in the name of Novartis. |                                    |                |                   |                                       |  |
| NOTE: Miles on appropriate time limit under 27 CED 4 404 or 4 405 has not been met, a notition to multiple /27 CED 4 427/s)   |  |                                    |                |                   |                                       |  |
| NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status. |  |                                    |                |                   |                                       |  |
| Send all correspondence to the address associated with  |  |                                    |                |                   |                                       |  |
| Customer No. 001095, which is currently:  |  |                                    |                |                   |                                       |  |
|   | <del>- 1</del>   |                                    |                | - <b>-</b>        | . ii                                  |  |
| Novaris   |  | gory D. Ferrard<br>rney for Applic |                |                   | ,                                     |  |
| Novartis<br>Corporate Intellectual Property   |  | . No. 36,134                       |                |                   |                                       |  |
| One Health Plaza, Building 104  |  | ?) 778-7831                        | . *            |                   | •                                     |  |
| East Hanover, NJ 07936-1080   |  |                                    |                |                   |                                       |  |



1095

**NOVARTIS** 

### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Viginia 22313-1450 www.uspto.gov

U.S. APPLICATION NUMBER NO.

FIRST NAMED APPLICANT

ATTY. DOCKET NO.

10/537,869

CORPORATE INTELLECTUAL PROPERTY

Francis Flat

PC/4-32818A

INTERNATIONAL APPLICATION NO. PCT/EP03/14406

I.A. FILING DATE

PRIORITY DATE

12/17/2003

12/18/2002

**CONFIRMATION NO. 6691 371 ACCEPTANCE LETTER** OC000000017310611\*

Date Mailed: 10/25/2005

ONE HEALTH PLAZA 104/3

EAST HANOVER, NJ 07936-1080

# NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

07/06/2005

07/06/2005

DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS

DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE. The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Copy of the International Application filed on 06/07/2005
- Copy of the International Search Report filed on 06/07/2005
- Copy of IPE Report filed on 07/06/2005
- Oath or Declaration filed on 07/06/2005
- U.S. Basic National Fees filed on 06/07/2005
- Priority Documents filed on 06/07/2005
- Power of Attorney filed on 07/06/2005
- Specification filed on 07/06/2005
- Claims filed on 07/06/2005
- Abstracts filed on 07/06/2005



Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

PAULETTE R KIDWELL Telephone: (703) 308-9140 EXT 216

PART 1 - ATTORNEY/APPLICANT COPY

FORM PCT/DO/EO/903 (371 Acceptance Notice)



1095

**NOVARTIS** 

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademar Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Vinginia 22313-1450

U.S. APPLICATION NUMBER NO.

FIRST NAMED APPLICANT

ATTY. DOCKET NO. PC/4-32818A

10/537,869

CORPORATE INTELLECTUAL PROPERTY

Giles Victor Campion

INTERNATIONAL APPLICATION NO.

PCT/EP03/14406

I.A. FILING DATE

PRIORITY DATE

12/17/2003

12/18/2002

**CONFIRMATION NO. 6691** 371 FORMALITIES LETTER \*OC000000017160708\*

Date Mailed: 10/06/2005

ONE HEALTH PLAZA 104/3

EAST HANOVER, NJ 07936-1080

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 06/07/2005
- Copy of the International Search Report filed on 06/07/2005
- U.S. Basic National Fees filed on 06/07/2005
- Priority Documents filed on 06/07/2005
- Specification filed on 06/07/2005
- Claims filed on 06/07/2005
- Abstracts filed on 06/07/2005

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

 Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice **MUST** be returned with the response.

DOCKETED FOR: Declo 2005

#### PAULETTE R KIDWELL

Telephone: (703) 308-9140 EXT 216

## PART 1 - ATTORNEY/APPLICANT COPY

| TO THE PART OF THE | INTERNATIONAL APPLICATION NO. | ATTY, DOCKET NO. |  |
|--|-------------------------------|------------------|--|
| U.S. APPLICATION NUMBER NO. 10/537,869   | PCT/EP03/14406                | PC/4-32818A      |  |

FORM PCT/DO/EO/905 (371 Formalities Notice)